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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/541,297

06/30/2005

Jurgen Kress

6636

60333

7590

11/07/2008

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EXAMINER

NIA, ALIREZA

ART UNIT

PAPER NUMBER

3739

MAIL DATE

DELIVERY MODE

11/07/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/541,297

**Applicant(s)**

KRESS, JURGEN

**Examiner**

ALIREZA NIA

**Art Unit**

3739

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 September 2008.  
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 29-48 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 29-48 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☒ The drawing(s) filed on 30 June 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO-8508)  
Paper No(s)/Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_  
5) ☐ Notice of Informal Patent Application  
6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(c), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(c) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 18<sup>th</sup>, 2008 has been entered.

### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. **Claims 29-48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

4. The recitations "and at a side of said cover facing away from a patient" in claims 29, 47, and 48 are indefinite since the "patient" cannot be part of the claim and without the patient as a reference, it is unclear which side the openings are located and in which direction they are facing. It is the Examiner's position that the claim recitation "faces away from a patient" in claims 29, 47, and 48 suggests necessary structure (for example a point of reference) that is a necessary "element" of the claimed invention, in order to determine, point out, and/or define the direction toward which the "opening" of the vacuum channel faces. In order to particularly point out and distinctly claim the subject matter, structural limitations other than a human or patient must be recited in the claims.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. **Claims 29, 30, 32-35, 38, 41-42, 46-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Silverstein 4,646,722 in view of Madni 6,007,482.**

7. With respect to claims 29, 41, 42, and 46, Silverstein discloses an endoscope 10,12 with hygiene protection, comprising a cover 48 closed at a distal end and transmissible for optical information via 32, at least on a front face of said cover 48, and capable of being rolled in an axial direction via 48 of said endoscope 10,12, a working channel 36,38,39 extending via 35 parallel to said endoscope 12 and terminating in an open mode via 36,40,42 at said distal end of said cover 48 (fig. 3), said working channel 36,38,39 being connected only to said distal end of said cover 48 and positioned between an outer side of said endoscope 12 and an inside of said cover 48 (col. 6, lines 39-42, col. 6, lines 62-65), wherein the at least one working channel 36,28,39 is fixed to said distal end 30 of said cover 48 (col. 6, lines 39-42).

8. However, Silverstein fails to positively disclose a vacuum channel, having at least one opening, and terminating at said inside of said cover and at a side of said cover that is an inner side of said cover and faces away from patient, said vacuum channel being a channel that is a different channel from said working channel.

9. Madni teaches a vacuum channel 29,30 in an analogous endoscope with hygiene protection, the vacuum channel 29,30 having at least one opening (fig. 2), and terminating at

inside of an analogous cover 16 and at a side of said cover 16 that is an inner side of said cover 16 and faces away from a patient, said vacuum channel 29,30 being a channel 29,30 that is a different channel from a working channel 61 (col. 2, lines 1-12, col. 2, lines 27-41, col. 3, lines 25-48). Madni further teaches means 49 for applying sub-atmospheric pressure to said at least one vacuum channel 29,30 during use of said endoscope. Madni further teaches at least one vacuum channel 29,30 extends for at least a portion of a length of said cover 16, wherein said vacuum channel 29,30 and working channel 61 are fixed to said distal end of said cover 16, resulting in an improved endoscope system which is flexible and has greater ease of cleaning having a unitary impermeable and stretchable flexible sheath which also form alternately inflatable bladders (col. 1, lines 30-33).

10. It would have been obvious to one of ordinary skill in the art at the time of the invention to have provided the endoscope of Silverstein with the above discussed limitations as taught by Madni in order to have provided an improved endoscope system which is flexible and has greater ease of cleaning having a unitary impermeable and stretchable flexible sheath which also form alternately inflatable bladders which facilitate and aid the maneuvering and propelling of the endoscope through tortuous curves of a human organ.

11. With respect to claims 30 and 33, Silverstein in view of Madni disclose the invention as discussed above. Silverstein further teaches that cover 48 is of an elastomeric material (col. 7, lines 56-58) therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have recognized that the elastomeric material of cover 48 would have obviously been the means for varying the cross-sectional diameter of cover 48; thus, allowing the inner

diameter of cover 48 to be larger than the outer diameter of the endoscope 10,12 (col. 7, lines 56-59).

12. With respect to claim 32, Silverstein in view of Madni disclose the invention as discussed above. Silverstein further teaches cover 48 is flexible and elastic and foldable in an axial direction of said endoscope (col. 6, lines 62-65).

13. With respect to claims 34 and 35, Silverstein in view of Madni disclose the invention as discussed above. Silverstein further teaches a transparent pane or lens 32 on said distal end 30 of said cover 48 on said front face of said cover 48 (col. 6, lines 1-3, fig. 2).

14. With respect to claim 38, Silverstein in view of Madni disclose the invention as discussed above. Silverstein further teaches the cover 48, when open at a proximal end, is fixable to be airtight on a shaft of said endoscope 10,12 (col. 7, lines 39-65).

15. With respect to claim 47, Silverstein discloses an endoscope 10,12 with hygiene protection, comprising a cover 48 closed at a distal end and transmissible for optical information via 32, at least on a front face of said cover 48, and capable of being rolled in an axial direction via 48 of said endoscope 10,12, a working channel 36,38,39 extending via 35 parallel to said endoscope 12 and terminating in an open mode via 36,40,42 at said distal end of said cover 48 (fig. 3), said working channel 36,38,39 being connected only to said distal end of said cover 48 and positioned between an outer side of said endoscope 12 and an inside of said cover 48 (col. 6, lines 39-42, col. 6, lines 62-65), wherein the at least one working channel 36,28,39 is fixed to said distal end 30 of said cover 48 (col. 6, lines 39-42). Silverstein also discloses the use of a coating on an inner side of said window 32 at said distal end 30 of said cover 48 for producing optical contact between said window 32 and an optical channel of said endoscope 10,12 (col. 6,

lines 55-57), the introduction of a distal end of said endoscope 10,12 into the cover 48, said cover 48 being open at a proximal end and closed at said distal end thereof via 32 (col. 6, line 58), rolling said cover 48 onto, or unfolding said cover 48 with, an enclosure of said endoscope 10,12 and said at least one working channel 36,38,39 (col. 6, lines 62-65).

16. However, Silverstein fails to positively disclose a vacuum channel, having at least one opening, and terminating at said inside of said cover and at a side of said cover that is an inner side of said cover and faces away from patient, said vacuum channel being a channel that is a different channel from said working channel. Silverstein also fails to disclose applying sub-atmospheric pressure to said vacuum channel.

17. Madni teaches a vacuum channel 29,30 in an analogous endoscope with hygiene protection, the vacuum channel 29,30 having at least one opening (fig. 2), and terminating at inside of an analogous cover 16 and at a side of said cover 16 that is an inner side of said cover 16 and faces away from a patient, said vacuum channel 29,30 being a channel 29,30 that is a different channel from a working channel 61 (col. 2, lines 1-12, col. 2, lines 27-41, col. 3, lines 25-48). Madni further teaches means 49 for applying sub-atmospheric pressure to said at least one vacuum channel 29,30 during use of said endoscope. Madni further teaches at least one vacuum channel 29,30 extends for at least a portion of a length of said cover 16, wherein said vacuum channel 29,30 and working channel 61 are fixed to said distal end of said cover 16, wherein sub-atmospheric pressure is applied to said vacuum channel 29,30 via 49, resulting in an improved endoscope system which is flexible and has greater ease of cleaning having a unitary impermeable and stretchable flexible sheath which also form alternately inflatable bladders (col. 1, lines 30-33).

18. It would have been obvious to one of ordinary skill in the art at the time of the invention to have provided the endoscope of Silverstein with the above discussed limitations as taught by Madni in order to have provided an improved endoscope system which is flexible and has greater ease of cleaning having a unitary impermeable and stretchable flexible sheath which also form alternately inflatable bladders which facilitate and aid the maneuvering and propelling of the endoscope through tortuous curves of a human organ.

19. With respect to the steps recited in method claim 47, where a reference discloses the terms of the recited method steps, and such steps necessarily result in the desired and recited effect, that the reference does not describe the recited effect *in haec verba* is of no significance as the reference meets the claim under the doctrine of inherency. Ex parte Novitski, 26 USPQ2d 1389, 1390-91 (BdPatApp & Inter 1993).

**20. Claims 31, 36 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Silverstein 4,646,722 in view of Madni 6,007,482 further in view of Sidall 4,741,326.**

21. Silverstein in view of Madni discloses the invention as discussed above. Madni further discloses an airtight, watertight, and impermeable to pathological microorganisms. However, Silverstein in view of Madni fails to positively disclose an airtight, watertight, and impermeable to pathological microorganisms with connection of said cover to said working channel to said distal end of said cover being made airtight, watertight, and impermeable to pathological microorganisms. Silverstein in view of Madni also fails to positively disclose the distal end of said cover is an optically transparent cap, wherein said distal end of said cover has a wall thickness that is greater than a wall thickness of a non-distal region of said cover.



22. Sidall teaches a protective sheath for use with endoscopes comprising an airtight, watertight, and impermeable to pathological microorganisms with connection of said cover 1 to a working channel 5,19 to said distal end of said cover being made airtight, watertight, and impermeable to pathological microorganisms that prevents the contamination of an endoscope (fig. 2, col. 2, lines 46-68, col. 3, lines 1-68). Sidall further teaches distal end 3 of said cover 1 is an optically transparent cap, wherein said distal end 3 of said cover has a wall<sup>3</sup> that is greater than a wall thickness of a non-distal region of said cover 1, resulting in an improved disposable protection device compatible with all endoscopes, eliminating the need for sterilization of the endoscope.

23. It would have been obvious to one of ordinary skill in the art at the time of the invention to have provided the device of Silverstein in view of Madni discussed limitations as taught by Sidall in order to have provided an improved disposable protection device compatible with all endoscopes while serving as a protective barrier to prevent bacterial and virus particles from coming into contact with the endoscope device, eliminating the need for sterilization of the endoscope.

24. **Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Silverstein 4,646,722 in view of Madni 6,007,482 further in view of Adair 5,433,221.**

25. Silverstein in view Madni discloses the invention as discussed above. However, Silverstein in view of Madni fails to positively disclose the cover to be conically enlarged in a vicinity of said proximal end with a portion of said cover being folded backwardly to be wrinkle-free in said vicinity of said proximal end and fixable via a chemically inert and non-toxic adhesive.

26. Adair teaches an analogous cover 10 used in covering an endoscopic surgical camera, the cover 10 having conically enlarged in a vicinity of its proximal end 12 (the distal end 14 having a smaller diameter than proximal end 12, col. 4, lines 33-42). The cover also having a portion 20 that is folded backwardly (col. 4, lines 55-59) wherein the proximal end 12 is fixable via an adhesive 18 (col. 4, lines 50-53) resulting in an improved sterile drape for an unsterile endoscopic camera system enhancing operating room procedures.

27. It would have been obvious to one of ordinary skill in the art at the time of the invention to have provided the device of Silverstein in view Madni with above discussed limitations as taught by Adair in order to have an improved sterile drape for an unsterile endoscopic camera system enhancing operating room procedures by minimizing sterility problems with an apparatus of this type that requires a minimal amount of handling to be put in use.

**28. Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Silverstein 4,646,722 in view of Madni 6,007,482 further in view of Darras 4,886,049.**

29. Silverstein in view of Madni disclose the invention as discussed above. However, Silverstein in view of Madni fail to disclose a tear thread connected to said cover at said distal end and running parallel to said endoscope on the inside of said cover.

30. Darras discloses a tear thread 20 attached to an endoscope cover 10 (col. 3, lines 1-20) and running parallel to said endoscope on an inside of the cover 10, resulting in an improved removing means for an endoscope cover which simplifies the cleaning and sterilization of endoscopes.

31. It would have been obvious to one of ordinary skill in the art at the time of the invention to have provided the device of Silverstein in view of Madni with the structure of the cover and

tear thread 20 as taught by Darras in order to have provided an improved removing means for an endoscope cover which simplifies the cleaning and sterilization of endoscopes to prevent the potential spread of viruses from one patient to another due to ineffective cleaning and sterilization of such instruments.

**32. Claims 43-44 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Silverstein 4,646,722 in view of Madni 6,007,482 further in view of Crawford 5,944,654.**

33. With respect to claim 43-44, Silverstein in view of Madni discloses the invention as discussed above. However, Silverstein in view of Madni fails to positively disclose depressions in an axial direction on an outer surface of said endoscope, said depressions corresponding in shape and in depth to a diameter and profile of said working channel and said vacuum channel, wherein said depressions have a width, running in the axial direction on said outer surface of said endoscope, which is smaller than the width of said depressions at their center points.

34. Crawford teaches depressions 20 in an axial direction on an outer surface of an analogous endoscope 10, said depressions 20 corresponding in shape and in depth to a diameter and profile of working channel 30 and vacuum channel 30 (col. 3, lines 40-48, col. 5, lines 12-20, figs. 1,2), wherein said depressions 20 have a width via 24, running in the axial direction on said outer surface of said endoscope 10, which is smaller than the width of said depressions at their center points (fig. 2), resulting in an improved endoscope apparatus having working and irrigation means which requires little or no internal space, does not substantially enlarge the diameter of the endoscope (col. 2, lines 15-19).

35. It would have been obvious to one of ordinary skill in the art at the time of the invention to have provided the endoscope system of Silverstein in view of Madni with the above discussed

limitations as taught by Crawford in order to have provided an improved endoscope apparatus having irrigation means which requires little or no internal space, does not substantially enlarge the diameter of the endoscope, wherein such configuration and arrangement renders the sterilization of the endoscope relatively easy and convenient.

36. With respect to claim 48, Silverstein discloses an endoscope 10,12 with hygiene protection, comprising a cover 48 closed at a distal end and transmissible for optical information via 32, at least on a front face of said cover 48, and capable of being rolled in an axial direction via 48 of said endoscope 10,12, a working channel 36,38,39 extending via 35 parallel to said endoscope 12 and terminating in an open mode via 36,40,42 at said distal end of said cover 48 (fig. 3), said working channel 36,38,39 being connected only to said distal end of said cover 48 and positioned between an outer side of said endoscope 12 and an inside of said cover 48 (col. 6, lines 39-42, col. 6, lines 62-65), wherein the at least one working channel 36,28,39 is fixed to said distal end 30 of said cover 48 (col. 6, lines 39-42). Silverstein also discloses the use of a coating on an inner side of said window 32 at said distal end 30 of said cover 48 for producing optical contact between said window 32 and an optical channel of said endoscope 10,12 (col. 6, lines 55-57), the introduction of a distal end of said endoscope 10,12 into the cover 48, said cover 48 being open at a proximal end and closed at said distal end thereof via 32 (col. 6, line 58), rolling said cover 48 onto, or unfolding said cover 48 with, an enclosure of said endoscope 10,12 and said at least one working channel 36,38,39 (col. 6, lines 62-65).

37. However, Silverstein fails to positively disclose a vacuum channel, having at least one opening, and terminating at said inside of said cover and at a side of said cover that is an inner side of said cover and faces away from patient, said vacuum channel being a channel that is a

different channel from said working channel. Silverstein also fails to disclose applying sub-atmospheric pressure to said vacuum channel.

38. Madni teaches a vacuum channel 29,30 in an analogous endoscope with hygiene protection, the vacuum channel 29,30 having at least one opening (fig. 2), and terminating at inside of an analogous cover 16 and at a side of said cover 16 that is an inner side of said cover 16 and faces away from a patient, said vacuum channel 29,30 being a channel 29,30 that is a different channel from a working channel 61 (col. 2, lines 1-12, col. 2, lines 27-41, col. 3, lines 25-48). Madni further teaches means 49 for applying sub-atmospheric pressure to said at least one vacuum channel 29,30 during use of said endoscope. Madni further teaches at least one vacuum channel 29,30 extends for at least a portion of a length of said cover 16, wherein said vacuum channel 29,30 and working channel 61 are fixed to said distal end of said cover 16, wherein sub-atmospheric pressure is applied to said vacuum channel 29,30 via 49, resulting in an improved endoscope system which is flexible and has greater ease of cleaning having a unitary impermeable and stretchable flexible sheath which also form alternately inflatable bladders (col. 1, lines 30-33).

39. It would have been obvious to one of ordinary skill in the art at the time of the invention to have provided the endoscope of Silverstein with the above discussed limitations as taught by Madni in order to have provided an improved endoscope system which is flexible and has greater ease of cleaning having a unitary impermeable and stretchable flexible sheath which also form alternately inflatable bladders which facilitate and aid the maneuvering and propelling of the endoscope through tortuous curves of a human organ.

40. However, Silverstein in view of Madni fails to positively disclose depressions in an axial direction on an outer surface of said endoscope, said depressions corresponding in shape and in depth to a diameter and profile of said working channel and said vacuum channel, wherein said depressions have a width, running in the axial direction on said outer surface of said endoscope, which is smaller than the width of said depressions at their center points.

41. Crawford teaches depressions 20 in an axial direction on an outer surface of an analogous endoscope 10, said depressions 20 corresponding in shape and in depth to a diameter and profile of working channel 30 and vacuum channel 30 (col. 3, lines 40-48, col. 5, lines 12-20, figs. 1,2), wherein said depressions 20 have a width via 24, running in the axial direction on said outer surface of said endoscope 10, which is smaller than the width of said depressions at their center points (fig. 2), resulting in an improved endoscope apparatus having working and irrigation means which requires little or no internal space, does not substantially enlarge the diameter of the endoscope (col. 2, lines 15-19).

42. It would have been obvious to one of ordinary skill in the art at the time of the invention to have provided the endoscope system of Silverstein in view of Madni with the above discussed limitations as taught by Crawford in order to have provided an improved endoscope apparatus having irrigation means which requires little or no internal space, does not substantially enlarge the diameter of the endoscope, wherein such configuration and arrangement renders the sterilization of the endoscope relatively easy and convenient.

43. With respect to the steps recited in method claim 48, where a reference discloses the terms of the recited method steps, and such steps necessarily result in the desired and recited effect, that the reference does not describe the recited effect *in haec verba* is of no significance as

the reference meets the claim under the doctrine of inherency. Ex parte Novitski, 26 USPQ2d 1389, 1390-91 (BdPatApp & Inter 1993).

**44. Claims 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Silverstein 4,646,722 in view of Madni 6,007,482 further in view of Oneda 5,518,501.**

45. Silverstein in view of Madni discloses the invention as discussed above. Madni further discloses that the distal end of vacuum channel 29,30 are detachable from distal end of cover 16 (since upon removal of 16, channels 29,30 are detached from the cover 16). However, Silverstein in view of Madni fails to positively disclose said working channel is detachably connected to said distal end of said cover.

46. Oneda teaches a cover 60 on an analogous endoscope, wherein at least two channels 106,108,110 are detachably connected to a distal end of the cover 60 (fig. 6), resulting in an improved endoscope that can be cleaned and disinfected with relative ease and little expense and wherein the components of the endoscope that are most difficult to clean and disinfect are disposable (col. 2, lines 62-67).

47. It would have been obvious to one of ordinary skill in the art at the time of the invention to have provided the system of Silverstein in view of Madni with the above discussed limitations as taught by Oneda in order to have provided an improved endoscope that can be cleaned and disinfected with relative ease and little expense and wherein the components of the endoscope that are most difficult to clean and disinfect are disposable, facilitating a quick turnaround of an operating room between surgical procedures.

***Response to Amendment***

48. The amendment to claims 29, 31, 41, 43, 45, and 46-48 in the response filed on September 18<sup>th</sup>, 2008 is acknowledged.
49. Claims 29-48 are pending in the application.

***Response to Arguments***

50. Applicant's arguments with respect to claims 29-48 have been considered but are moot in view of the new ground(s) of rejection.
51. Applicant's arguments filed September 18<sup>th</sup>, 2008 with respect to the rejection of claims 29-48 under 35 USC § 112, second paragraph rejection presented in the Final Office Action mailed on March 18<sup>th</sup>, 2008 have been fully considered but they are not persuasive. In response to Applicant's argument that *"As part of the indefiniteness rejection of the final Office Action, the Examiner also objected to the use of the "patient" as a reference in Applicant's claims, contending that a "patient," or presumably any "person," cannot be part of a claim. The Examiner's position, as best understood by Applicant's counsel, is correct, as a general proposition, but misapplied in this instance to the present Applicant's claims: While a human being can neither be "claimed" as an "invention," nor be an "element" of any claimed invention, there is no prohibition against reciting a "person," per se, in a claim as a point of reference. In this respect, as examples, the Examiner is referred to the following patents which make reference to a person as part of claiming the invention disclosed therein: 1. Jannard et al., U.S. Patent No. 6,325,507, issued December 4, 2001, discloses an "eyewear retention system extending across the top of a wearer's head." 2. Binder et al., U.S. Patent No. 7,297,128, issued November 20, 2007, which discloses an "arm suspension sleeve," and, which the Abstract of this patent*



*explains, provides "more comfortable gel treatment to the skin." A wide-range of inventions are used by humans and the patents disclosing these types of inventions invariably recite humans as reference points for whom such inventions are so intended.*", the Examiner disagrees with Applicant since the claim recitation "faces away from a patient" in claims 29, 47, and 48 suggests necessary structure (for example a point of reference) that is a necessary "element" of the claimed invention, in order to determine, point out, and/or define the direction toward which the "opening" of the vacuum channel faces. In order to particularly point out and distinctly claim the subject matter, structural limitations other than a human or patient must be recited in the claims. Furthermore, the Jannard 6,325,507 reference cited by the Applicant recites the following in the independent claim 1 "An eyewear support, comprising an elongate arcuate frame having a frontal end and an occipital end, dimensioned to extend across the top of the head of a wearer from the glabellar region to the vicinity of the external" (see claim 1, Jannard). Thus, Jannard does not use the head of a wearer (the patient, subject, etc.) as a reference point. The Binder 7,297,128 reference does not use the body or a patient as a reference point. Accordingly, the Jannard and Binder references are not sufficient as evidence to overcome the indefiniteness rejection.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALIREZA NIA whose telephone number is (571)270-3076. The examiner can normally be reached on Mo.-Fri.-7:30 AM-5:00 PM EST-Alternate Fridays Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/A. N./  
Examiner, Art Unit 3739  
Alireza Nia  
October 30<sup>th</sup>, 2008

/Linda C Dvorak/  
Supervisory Patent Examiner, Art Unit 3739